The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 33

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U.S. PATENT AND TRADEMARK OFFICE BOARD OF PATENT APPEALS AND INTERFERENCES

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JOHN H. BURTON and TIMOTHY C. COOK

Appeal No. 2004-1462 Application No. 09/477,977

HEARD: JANUARY 26, 2005

Before FRANKFORT, PATE and BAHR, Administrative Patent Judges. BAHR, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1-24, 26-37, 39 and 40. Claims 25 and 38, the only other claims pending in this application, stand objected to as being dependent upon a rejected base claim.

<u>BACKGROUND</u>

The appellants' invention relates to an implantable device and method for adjustably restricting a body lumen by placing an expandable element adjacent the body lumen. Expansion of the expandable element to cause displacement of the body

tissue adjacent the body lumen so as to adjustably restrict or coapt the lumen is accomplished by delivering a fluid material into a rear port of the implantable device remote from the expandable element but near the patient's skin, thus enabling post-operative adjustment with minimal invasiveness (specification, page 1). A copy of the claims under appeal is set forth in the appendix to the appellants' brief.

The examiner relied upon the following prior art references of record in rejecting the appealed claims:

Hickey et al. (Hickey)	4,553,959	Nov. 19, 1985
Whitehouse et al. (Whitehouse)	4,559,043	Dec. 17, 1985
Haber	4,846,784	Jul. 11, 1989
McIntyre et al.	5,334,153	Aug. 2, 1994
Salama	5,634,877	Jun. 3, 1997
Andino et al. (Andino)	5,637,074	Jun. 10, 1997

The following rejections are before us for review.

Claims 1, 3, 5, 6 and 8 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Hickey.

Claims 13-17, 19-24, 27-32, 34-37, 39 and 40 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Haber.

Claims 2 and 7 stand rejected under 35 U.S.C. § 103 as being unpatentable over Hickey in view of Whitehouse.

Claim 4 stands rejected under 35 U.S.C. § 103 as being unpatentable over Hickey in view of McIntyre.

Claims 9 and 10 stand rejected under 35 U.S.C. § 103 as being unpatentable over Hickey.

Claims 11 and 12 stand rejected under 35 U.S.C. § 103 as being unpatentable over Hickey in view of Whitehouse and Salama.

Claims 18 and 33 stand rejected under 35 U.S.C. § 103 as being unpatentable over Haber in view of Andino.

Claim 26 stands rejected under 35 U.S.C. § 103 as being unpatentable over Haber in view of Whitehouse.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejections, we make reference to the final rejection and the answer (Paper Nos. 10 and 20) for the examiner's complete reasoning in support of the rejections and to the brief and reply brief (Paper Nos. 19 and 21) for the appellants' arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references, and to the respective positions articulated by the appellants and the examiner. As a consequence of our review, we make the determinations which follow.

Claim 1 is directed to an "implantable device" comprising, inter alia, a pressurizable expandable element, wherein the implantable device is "adapted for

implantation within body tissue with the expandable element adjacent a body lumen to provide volume to the body tissue for adjustable coaptation of the body lumen." Claim 8 likewise recites, in combination with an elongate probe member adapted for insertion into tissue adjacent a body lumen, an elongate implantable device "adapted for being surgically implanted into the tissue adjacent to the body lumen." Appellants (brief, page 6) argue that the Hickey catheter, which is inserted into the urethra and catheter for drainage of urine, is not "adapted for implantation within body tissue with the expandable element adjacent a body lumen to provide volume to the body tissue for adjustable coaptation of the body lumen," as recited in claim 1, or "adapted for being surgically implanted into the tissue adjacent to the body lumen," as recited in claim 8. The examiner contends that, based on the broad definition of "implant" in <u>Stedman's Medical Dictionary</u> as "to graft or insert," Hickey's catheter "is implanted into the urethra, which constitutes being implanted into tissue" (answer, page 4).

While it is true that the claims in a patent application are to be given their broadest reasonable interpretation consistent with the specification during prosecution of a patent application (see, for example, In re Zletz, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989)), it is also well settled that terms in a claim should be construed as those skilled in the art would construe them (see Specialty Composites v. Cabot Corp., 845 F.2d 981, 986, 6 USPQ2d 1601, 1604 (Fed. Cir. 1988) and In re Johnson, 558 F.2d 1008, 1016, 194 USPQ 187, 194 (CCPA 1977). In this instance, a

person of ordinary skill in the surgical art, having read appellants' specification, and in particular the disclosure of the implantation of the device on pages 20-24 and illustration in Figures 4-8, would understand the language "implantation within body tissue with the expandable element adjacent a body lumen" to mean placement of the device, via an ultimately closed incision within tissue, such that it is completely enclosed within tissue, rather than simply placed within a body lumen. Such a person would not envisage implanting Hickey's catheter within or into body tissue in this manner and, thus, would not reasonably consider Hickey's urinary catheter to be "adapted for implantation within body tissue with the expandable element adjacent a body lumen" as called for in claim 1 or "adapted for being surgically implanted into the tissue adjacent the body lumen" as called for in claim 8

For the foregoing reason, we cannot sustain the examiner's rejection of independent claims 1 and 8, or claims 3, 5 and 6 which depend from claim 1, as being anticipated by Hickey. We likewise cannot sustain the examiner's rejection of claims 9 and 10, which depend from claim 8, as being unpatentable over Hickey. The examiner's application of Whitehouse, McIntyre and Salama in rejecting the remaining claims depending from claims 1 and 8 does not remedy the above-mentioned deficiency of Hickey. It thus follows that we also cannot sustain the examiner's rejection of claims 2 and 7 as being unpatentable over Hickey in view of Whitehouse,

claim 4 as being unpatentable over Hickey in view of McIntyre, and claims 11 and 12 as being unpatentable over Hickey in view of Whitehouse and Salama.

Appellants' claims 13 and 28 are directed to a method for variably restricting a body lumen in a patient comprising guiding an elongate implantable device into body tissue of a patient to a location adjacent a body lumen to be restricted using an elongate probe member, the implantable device having an expandable element located at its forward end and having a port portion at its rearward end and providing a flowable material from a source into the port portion, so as to expand the expandable element to at least partially restrict the body lumen. Appellant argues that Haber fails to show "providing a flowable material from a source into the port portion at the rearward end of the elongate implantable device, as recited in claim 13" and "providing a flowable material at the rearward end from a source into the port portion, so as to expand the expandable element to at least partially restrict the body lumen, as recited in claim 28" because Haber, in contrast, "appears to show a hypodermic needle delivering directly to balloon 2" (brief, page 7).

The rearward end of the proximal tubing 22 of Haber responds structurally to the "port portion" provided at the rearward end of the device referred to in claims 13 and 28. The essence of appellants' argument appears to be that, in Haber's method, the fluid or suspended particles (flowable material) is delivered from the hypodermic needle via a cannula 4 which extends into and through the proximal tubing 22 all the way to

the occlusion balloon 2. In our view, this delivery step provides the fluid or suspended particles from a source (the hypodermic needle) into¹ the rearward end of proximal tubing 22, notwithstanding that the fluid or suspended particle material is also within the cannula when it enters into the tubing 22. Further, this delivery of fluid or suspended particle material causes expansion of the expandable element to at least partially restrict the body lumen (i.e., the urethra - see col. 5, lines 38-51) as recited in claims 13 and 28. We see nothing in appellants' claims 13 and 28 which requires that the flowable material contact the walls of the device or reside within the port portion for any length of time.

For the foregoing reason, we find appellants' argument with regard to claims 13 and 28 unpersuasive. The rejection of claims 13 and 28, as well as claims 14-17, 19-24, 27, 29-32, 34-37, 39 and 40 which depend therefrom and are not separately argued apart from claims 13 and 28, as being anticipated by Haber is affirmed. The rejections of claims 18 and 33 as being unpatentable over Haber in view of Andino and claim 26 as being unpatentable over Haber in view of Whitehouse are also affirmed, inasmuch as appellants' only argument against these rejections is the purported deficiency of Haber discussed above with respect to claims 13 and 28.

¹ The term "into" is defined as "from the outside to the inside of; toward and within." <u>Webster's New World Dictionary</u>, Third College Edition (Simon & Schuster, Inc. 1988).

CONCLUSION

To summarize, the decision of the examiner is affirmed as to claims 13-24, 26-37, 39 and 40 and reversed as to claims 1-12.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED-IN-PART

CHARLES E. FRANKFORT Administrative Patent Judge

JENNIFER D. BAHR

Administrative Patent Judge

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PATE, Administrative Patent Judge, concurring-in-part and dissenting-in-part,

While I join with my colleagues as to the disposition of the apparatus claims, claims 1-12, and many of the method claims, I dissent with respect to the disposition of some of the method claims on appeal, viz., independent claim 13 and the claims dependent thereon. Claim 13 includes the method step limitation of: "providing a flowable material from a source into the port portion,...."

Turning to the Haber patent, it is a simple matter to see that the source, cannula 4, provides fluid into expandable element 2 and not into the rear of the device or the reservoir 20, whichever is construed as the port portion. The construction of this limitation of claim 13 seems to me to be rather straightforward and I do not consider flow through a cannula inserted through a port portion to be flow "into the port portion."

I would reverse the rejections of claim 13 and the claims dependent thereon in which Haber is used either as an anticipatory reference or as evidence of obviousness under 35 U.S.C. § 103.

WILLIAM F. PATE, III

Administrative Patent Judge

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SCHWEDGMAN, LUNDBER, WOESSNER & KLUTH, P.A. PO BOX 2938
MINNEAPOLIS, MN 55402

IN THE UNIT STATES PATENT AND TRADEMARK CIC

AF/135 3739

Applicant:

John H. Burton et al.

Title:

IMPLANTABLE DEVICE AND METHOD FOR ADJUSTABLY RESTRICTING A BODY

LUMEN

Docket No.:

825.001US2

Filed: Examiner:

January 5, 2000 R. Kearney

.

Serial No.: 09/477,977 Due Date: May 3, 2005

Group Art Unit: 3739

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

We are transmitting herewith the following attached items (as indicated with an "X"):

X A return postcard.

X Amendment Pursuant to 37 CFR 41.50 (9 Pages).

If not provided for in a separate paper filed herewith, Please consider this a PETITION FOR EXTENSION OF TIME for sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

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<u>CERTIFICATE UNDER 37 CFR 1.8:</u> The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this <u>3rd</u> day of May, 2005.

PATRICIA A. HULTMAN

Name

Signature

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

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